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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,990	09/19/2003	Michael A. Apicella	17023-031001 / 01025	5383

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,990	APICELLA ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-28* is/are pending in the application.

4a) Of the above claim(s) *7,8,17-22 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-16,25,26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/30/06,1/10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment

1. The amendment and response to restriction filed on 2/27/06 and is acknowledged.

Election/Restriction

2. Applicant's election with traverse of Group III, Claims 19-11 SEQ ID N0: 14 is acknowledged. The traversal is on the ground(s) that all groups should be examined as the search and examination of the other groups would not be an undue burden.
This is not found persuasive because MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required. Restrictions between the inventions, is deemed to be proper for the reasons previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case, the restriction of sequences has acquired a separate status in the art as a separate subject for inventive effect and requires independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. However, The examiner included group IV, vaccine claims 12-16 to the elected invention, polypeptide 9-11, 25, 26 and 28.

Status of Claims

3. Claims 12-22 have been amended.

Claims 1-6 and 23-24 are cancelled.

New claims 25-28 have been added.

Claims 9-16, 25,26 and 28 are under examination as an elected invention, drawn to polypeptide.

Claims 7-8, 17-22 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected group of inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement

Priority

4. This application 10/665,990 is a CIP of 10/621,184 07/15/2003 ABN which is a CIP of 10/066,551 01/31/2002 which claims benefit of 60/266,070 01/31/2001 and claims benefit of 60/310,356 08/06/2001and claims benefit of 60/344,452 10/23/2001.

Information Disclosure Statement

5. Information Disclosure Statements filed on 7/30/04 and 7/10/05 are acknowledged. The examiner has reviewed the IDS and a signed copy of each is attached to this Office action.

Drawings

6. The drawings filed on 9/19/03 have been accepted by the examiner.

Specification Informalities

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see in particular at least page 27.
Applicant is required to delete the embedded hyperlink and/or other form of browser- executable code. See MPEP § 608.01.

Claim rejection 35 USC 112, first paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 10, 12-16 (vaccine composition) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claims are evaluated for enablement using the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the disclosed invention is drawn to a vaccine composition for the treatment or cure of a disease or prevention of an infection caused by *Neisseria gonorrhea.* The state of the art indicates (Barritt et al, Infect and Immu1987, 55:2026-2031) the outermembrane protein antigens of *N.gonorrhoeae* are highly variable. The family of proteins that show variation are the surface exposed proteins II (P II) and Opa proteins. These variations enable the bacterium to evade the host immune response and adapt to differing host environment.

Both pilin and Opa proteins undergo considerable variation in vivo as inoculation of strains FA1090 and strain MS11 with Opa negative population of gonococci resulted in reisolation of mostly Opa positive gononcocci indicating that there is a strong selection for expressing Opa proteins in vivo (see IDS,8/9/04 Cohen and Canon, JID 1999, 179(suppl) S375 –379).

However, experimental studies are only pursued in men, since the complications in women

would outweigh any potential benefits. The specification on pages 68- 78 recite that the antibodies to CR3, CD18 inhibit the binding of Neisseria to cervical epithelial cells. However, as claimed protein comprising the amino acid sequence SEQ.ID.NO: 14 (strains, MS11 and strain 1291, encoding secretion system) would directly inhibit the infectivity has not been shown. An isolated phospholipase D polypeptide antibody has the ability to block the infection of cervical cells (endocervical or ectocervical cells) by blocking the access of *N. gonorrhoeae* to the CR3receptor on the surface of the cell (specification at page 48, lines 26 to page 49, line 2). However, the claimed isolated and purified polypeptide comprising the amino acid sequence as set forth in SEQ.ID.NO: 14 or an isolated polypeptide encoded by the nucleic acid sequence SEQ. ID.NO: 13 would effectively prevent, ameliorate, or reduce the incidence of all *N gonhorrhoeae* strains in established ex vivo model system has not been disclosed. It is unpredictable whether the claimed composition induces an immune response sufficient to inhibit gonorrhea disease caused by various clinical strains of *Neisseria gonorrhea* because the prior art discloses that the human pathogen *N.gonorrhoeae* is endowed with a wide range of mechanisms that facilitate immune avoidance including antigenic shift in the expression of surface antigens. Because of this antigenic shift the development an effective vaccine has resulted in frustrated attempts (see introduction of Paz et al 1995, Microbiology 141, 913-920, reference cited in Form 892, 7/20/03). The specification has not disclosed a link or nexus between the generation of protective immunity and the claimed polypeptide. Further, it is not routine in the art to use the claimed compositions for this purpose. Accordingly, there is no objective basis upon which the skilled artisan would reasonably be able to determine or predict an amount of the claimed vaccine effective for its intended use. Therefore, undue experimentation would be required to make and use the invention.

Claim Rejections - 35 USC 112, second paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 9, 10, 11, 25, 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 is rejected as being vague for the recitation of "nucleic acid sequence SEQ.ID.NO: 9, 15, 17 etc " because applicant's election is drawn to an isolated and purified polypeptide comprising the amino acid sequence SEQ.ID.NO: 14 " Does applicant intend to mean an isolated and purified polypeptide comprising the amino acid sequence SEQ.ID.NO: 14 encoded by the nucleic acid sequence SEQ.ID.NO: 13?

Claim 10 is rejected as being vague for the recitation of "comprising " phospholipase D " Does applicant intend to mean an isolated and purified phospholipase D polypeptide from *Neisseria gonorrhea* comprising the amino acid sequence SEQ.ID.NO: 14?

Claim 11 is rejected as being vague for the recitation of "comprises SEQ.ID.NO: 4, SEQ.ID.NO: 14 etc " Does applicant intend to mean the polypeptide of claim 10, wherein the polypeptide comprises the amino acid sequence SEQ.ID.NO: 14?

Claim Rejections - 35 USC 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 10, 11, 12-16, 25, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Paz et al (1995, Microbiology 141, 913-920)

Examiner is viewing the vaccine as a composition.

Paz et al disclose outermembrane proteins from *N.gonorrhoeae* strain p9. (see page 914, right column under Methods, first paragraph). Outer membrane proteins (OMP) from *N.gonorrhoeae would* inherently contain the claimed protein and several other proteins that are linked together Monoclonal antibodies were directed against polysaccharides and outermembrane proteins (see page 914, right column under Methods, second paragraph) indicating that the composition is immunogenic. It is routine in the art to use adjuvants such as CFA for immunizing mice for raising antibodies. Applicant's use of the open-ended term "comprising " in the claims 10 and 11 fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed OMP from *N.gonorrhoeae*. Characteristics such as amino acid sequence as set forth in the SEQ.ID.NO: 4 are considered inherent properties of the outer membrane proteins and proteins are encoded by nucleic acids. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art anticipates the claimed invention. Since the Office does not have the facilities for examining and comparing applicant's claimed isolated polypeptide comprising phospholipase D from a *Neisseria* bacterium or isolated polypeptide comprising SEQ.ID.NO: 14 with the outer membrane protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior

art. Here, the prior art discloses the same composition and formulations thereof as claimed. Thus, the prior art anticipated the claimed invention.

It is acknowledged that weight is given to every term in claims 12-16. This is why the instant claims drawn to vaccine are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the immunogenic composition i.e., vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. However, under prior art rejections, the term vaccine is considered as a composition comprising an isolated polypeptide. See In re Best, 562 F. 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

14. Claims 9-16, 25, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Fraser et al 1999, Accession Number AAY 75751 or AAY 75753.

The claims are discussed supra.

Fraser et al disclose a novel polypeptide from *N.gonorrhoeae*. (See the attached sequence alignment, SEQ.ID.NO: 14 and abstract) comprising an amino acid sequence, which is 95.1% similar to the claimed SEQ.ID.NO: 14. This polypeptide is encoded by nucleic acid sequence (See the attached sequence alignment, SEQ.ID.NO: 13) and is 90.7% identical to the claimed sequence. The polypeptide could be used as vaccine, immunogenic composition or to raise antibodies (see abstract). The antigen to which an immune response has to be elicited is in general in hydrophilic phase, buffer or saline and is routinely used in the art. Characteristic such as Phospholipase D is considered as the inherent property of the disclosed polypeptide that is encoded by nucleic acid. In the absence of evidence to the contrary the disclosed prior art anticipated the claimed invention.

It is acknowledged that weight is given to every term in claims 12-16. This is why the instant claims drawn to vaccine are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the immunogenic composition i.e., vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. However, under prior art rejections, the term vaccine is considered as a composition comprising an isolated polypeptide. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

15. Claims 9-16, 25, 26 and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Parkhill 2000, Accession Number B81859.

The claims are discussed supra.

Parkhill et al disclose a novel polypeptide from *N.meningitidis.* (see the attached sequence alignment, SEQ.ID.NO: 14 and abstract) comprising an amino acid sequence, which is 97.2% similar to the claimed SEQ.ID.NO: 14. This polypeptide is encoded by nucleic acid sequence (See the attached sequence alignment, SEQ.ID.NO: 13) and is 92.2% identical to the claimed sequence. Characteristic such as Phospholipase D is considered as the inherent property of the disclosed polypeptide that is encoded by nucleic acid. Since this polypeptide is 100%identical to the claimed polypeptide the source from which it is isolated is considered as a product by process claim. When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different source. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113. Thus, the prior art anticipated the claimed invention.

It is acknowledged that weight is given to every term in claims 12-16. This is why the instant claims drawn to vaccine are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the immunogenic composition i.e., vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. However, under prior art rejections, the term vaccine is considered as a composition comprising an isolated polypeptide. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Remarks

16. No claims are allowed.

17. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A

message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

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